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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/646,807	12/05/2000	Michael Wayne Graham	DAVI105.001A	1584

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EXAMINER	
WHITEMAN, BRIAN A	

ART UNIT	PAPER NUMBER
1635	

DATE MAILED: 06/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/646,807	GRAHAM ET AL.	
	Examiner	Art Unit	
	Brian Whiteman	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12/7/04, 3/10/05*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *27, 28, 34-38 and 48-64* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *27. 28. 34-38. 48-64* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *2/11/05, 2/25/05, 6/30/05* 12/8/06, 11/8/04
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114 was filed in this application after appeal to the Board of Patent Appeals and Interferences, but prior to a decision on the appeal. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 12/7/04 has been entered.

Non-Final Rejection

Claims 27, 28, 34-38, and 48-64 are pending.

The amendment to the specification on 12/27/05 is acknowledged.

The amendment to claims 27-28, 34-38 and 48 filed on 3/10/05 is acknowledged and considered by the examiner.

Applicant's traversal, the amendment to claims 27-28, 34-38 and 48 and the addition of claims 49-64 filed on 12/7/04 is acknowledged and considered by the examiner.

The examiner of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be to directed to Brian Whiteman, Art Unit 1635.

Priority

Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed application, Application No. 09/100,812, fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application.

Instant claims 59 and 60 do not have written support under 112 first paragraph for wherein said region of a genus of target genes is 20 to 30 (at least 30) nucleotides long. The specification of '812 contemplates: "at least about 20-30 nucleotides in length derived from a viral DNA polymerase, viral RNA polymerase, viral coat protein, or visually-detectable gene, more particularly an RNA polymerase gene derived from a virus selected from the list comprising BEV, Sinbis alphavirus, HIV-1, bovine herpes virus and HSV1 or a visually detectable gene which is involved in determining pigmentation, cell death or other external phenotype on a cell, tissue, organ, or organism, amongst others" and "the structural gene component of the synthetic gene comprises at least about 20-30 nucleotides in length derived

from the BEV RNA-dependent RNA polymerase gene or the murine tyrosinase gene or the Escherichia coli lac repressor gene lacI or a complementary sequence thereto." See column 6, lines 25-40.

Instant claim 34 does not have written support under 112 first paragraph for the limitation "the target gene is α-1,3-galactosyltransferase".

Instant claims do not have written support under 112 first paragraph for the limitation "target gene is derived from the genome of a pathogen of the human cell or the genome of the human cell".

Information Disclosure Statement

The examiner has considered the international and European search report and examination reports have been considered, but the reports have not been initialed because they are not considered published documents.

Exhibit A and B have been acknowledged by the examiner. However, the examiner has not considered the references since the 4558 references in Exhibit A or the 270+ references cited in Exhibit B have not been listed on a PTO-1449. The information disclosure statement filed 2/11/05 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. The exhibits have been placed in the application file, but the information referred to therein has not been considered.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 48-64 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

New matter rejection:

As stated above, claims 48-64 were new claims filed on 12/7/04. Applicants did not provide support for the new claims. The examiner thoroughly searched the instant specification and could not find support for the instant claims. Therefore, there does not appear to be a written description of the new claims in the application as filed. See MPEP § 2163.06.

Claims 27, 28, 34-38, 48-51, and 53-64 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 27, 28, 34-38, 48-51, and 53-64, as best understood, is readable on a genus of structural gene sequence comprises a nucleotide sequence which is at least 80% identical to the

sequence to the sequence of the target gene or region thereof, wherein the genus of structural gene sequences is not claimed in a specific biochemical or molecule structure that could be envisioned by one skilled in the art at the time the invention was made.

The specification contemplates a target gene which is endogenous to an animal cell or a foreign gene such as a viral or foreign genetic sequence (page 7). The disclosure provides sufficient description for the target gene is α-1,3-galactosyltransferase. The specification further provides support for a structural gene component of the synthetic gene comprises derived from the BEV RNA-dependent RNA polymerase gene or the murine tyrosinase gene or the Escherichia coli lac repressor gene lacI. However, the specification does not provide sufficient description of a genus of a structural gene sequence comprises a nucleotide sequence, which is at least 80% identical to the sequence of the target gene or region thereof and is capable of post-transcriptionally delaying, repressing or otherwise reducing the expression of a target gene in a human cell. There is a variation between the species embraced by the claimed genus and function. The specification does not disclose how to make a representative number of species of the claimed genus with the desired biological function. The prior art does not supplement how to make a representative number of species of the claimed genus with the desired biological function. The skilled artisan would understand that not all sequences embraced by the claimed genus can initiate degradation of target gene or region thereof. It is not apparent that on the basis of the applicants' disclosure, an adequate written description of the invention defined by the claims requires more than a mere statement that it is part of the claimed invention and reference to potential methods and/or molecular structures of molecules that are essential for the genus of

structural gene sequences comprises a nucleotide sequence that must exhibit the disclosed biological functions as contemplated by the specification.

It is not sufficient to contemplate a genus of target gene or region thereof to support the present claimed invention directed to a genus of structural gene sequence comprises a nucleotide sequence which is at least 80% identical to the sequence of the target gene or region thereof. The claimed invention as a whole is not adequately described if the claims require essential or critical elements, which are not adequately described in the specification and which is not conventional in the art as of applicant's effective filing date. Claiming a genus of structural genes that must possess the biological properties as contemplated by applicant's disclosure without defining what means will do so is not in compliance with the written description requirement. Rather, it is an attempt to preempt the future before it has arrived. (See *Fiers v. Revel*, 25 USPQ2d 1601 (CA FC 1993) and *Regents of the Univ. Calif. v. Eli Lilly & Co.*, 43 USPQ2d 1398 (CA FC, 1997)). Possession may be shown by actual reduction to practice, clear depiction of the invention in a detailed drawing, or by describing the invention with sufficient relevant identifying characteristics such that a person skilled in the art would recognize that the inventor had possession of the claimed invention. Pfaff v. Wells Electronics, Inc., 48 USPQ2d 1641, 1646 (1998). The skilled artisan cannot envision the detailed structure of a genus of structural genes that must exhibit the contemplated biological functions, and therefore, conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the structures and/or methods disclosed in the as-filed specification. Thus, in view of the reasons set forth above, one skilled in the art at the time the invention was made

would not have recognized that applicant was in possession of the claimed invention as presently claimed.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The limitation "capable of post-transcriptionally delaying, repressing or otherwise reducing expression of a target gene in a mammalian cell by sequence-specific degradation of a RNA transcript of the target gene by an endogenous system of the mammalian cell" in instant claims 27 and 56-58 and claims dependent therefrom are directed to an intended use of the product. With regard to the specified activity, if a prior art structure is capable of performing the intended use as recited in the claim, then it meets the claim. See, e.g., In re Schreiber, 128 F.3d 1473, 1477, 44 USPQ2d 1429, 1431 (Fed. Cir. 1997).

The term "capable" in the limitation recited in instant claims 27 and 56-58 and claims dependent therefrom does not require that the construct perform the functions recited in the claimed product.

Claims 27, 28, 36, 37 remain and claims 38, 49-53, 55, and 56-61 are rejected under 35 U.S.C. 102(b) as being anticipated by Dorer (1994) 77:993-1002 (IDS filed on 5/14/01). The rejection applies for the reason of record on pages 9-10 of office action mailed on 12/17/03.

Applicant's arguments filed 12/7/04 have been fully considered but they are not persuasive for because they were already addressed on pages 9-10 of office action mailed on 12/17/03.

Claims 27, 28, and 38 remain and claims 49-53, 56, and 59-64 are rejected under 35 U.S.C. 102(e) as being anticipated by Fire et al. (US 6,506,559). Fire teaches a vector comprising a construct comprising a promoter operably linked to a nucleotide sequence comprising a sense strand and an antisense strand of the target gene (columns 4 and 9). The promoter can be a T7 and T3 promoters (columns 8-9). The nucleotide sequence may be at least 25 or 50 bases (column 8). The vector can be introduced into a cancerous cell, including cancer cells find in humans (column 9-10). A viral vector can be used as the vector (column 9). The cell can comprise a target gene at risk from a pathogen including HIV (columns 4, 8, and 10). The target gene can be an endogenous from in a human cell (columns 4 and 10-11). The structural gene can comprise one or more strands of the nucleotide sequence (column 4).

Applicant's arguments filed 12/7/04 have been fully considered but they are not persuasive for the reasons of record.

Applicant's argument directed to the claimed methods is moot because the methods claims were cancelled.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 57 and 59-64 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fire et al (US 6,506,559, cited on a PTO-~~1449~~ SB/8) taken with Conrad (US 6,054,299). Fire teaches a vector comprising a construct comprising a promoter operably linked to a nucleotide sequence comprising a sense strand and an antisense strand of the target gene (columns 4 and 9). The promoter can be a T7 and T3 promoters (columns 8-9). The nucleotide sequence may be at least 25 or 50 bases (column 8). The vector can be introduced into a cancerous cell, including cancer cells find in humans (column 9-10). A viral vector can be used as the vector (column 9). The

cell can comprise a target gene at risk from a pathogen including HIV (columns 4, 8, and 10). The target gene can be an endogenous from in a human cell (columns 4 and 10-11). The structural gene can comprise one or more strands of the nucleotide sequence (column 4). The vector can be in combination with a carrier (column 14). However, Fire does not specifically teach a construct comprising one promoter operably linked to a nucleotide sequence comprising the sense strand and another promoter operably linked to a nucleotide encoding comprising the antisense strand.

However, at the time the invention was made, Conrad teaches a vector comprising T7 and T3 promoters (Figure 1, Column 7).

It would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to combine the teaching of Fire taken with Conrad, namely to produce a vector comprising one promoter operably linked to a nucleotide sequence comprising the sense strand and another promoter operably linked to a nucleotide encoding comprising the antisense strand. One of ordinary skill in the art would have been motivated to combine the teaching to isolate either single stranded antisense strand or single stranded sense strand.

In addition, it would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to combine the teaching of Fire taken with Conrad, namely to produce an isolated animal cell comprising a vector comprising one promoter operably linked to a nucleotide sequence comprising the sense strand and another promoter operably linked to a nucleotide encoding comprising the antisense strand. One of ordinary skill in the art would have been motivated to combine the teaching for isolating either single stranded antisense strand or single stranded sense strand.

Therefore the invention as a whole would have been *prima facie* obvious to one ordinary skill in the art at the time the invention was made.

Claims 56 and 58-64 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fire et al (US 6,506,559, cited on a PTO-1449) taken with Ladner et al (US 5,198,346). Fire teaches a vector comprising a construct comprising a promoter operably linked to a nucleotide sequence comprising a sense strand and an antisense strand of the target gene (columns 4 and 9). The promoter can be a T7 and T3 promoters (columns 8-9). The nucleotide sequence may be at least 25 or 50 bases (column 8). The vector can be introduced into a cancerous cell, including cancer cells find in humans (column 9-10). A viral vector can be used as the vector (column 9). The cell can comprise a target gene at risk from a pathogen including HIV (columns 4, 8, and 10). The target gene can be an endogenous from in a human cell (columns 4 and 10-11). The structural gene can comprise one or more strands of the nucleotide sequence (column 4). However, Fire does not specifically teach separating a construct comprising the structural gene sequences with a stuffer sequence.

However, at the time the invention was made, Lander teaches using a stuffer fragment having above about 10 nucleotides to introduce a stop codon or a unique restriction site (column and Table 704).

It would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to combine the teaching of Fire taken with Ladner, namely to produce a construct comprising a structural gene with a stuffer sequence. One of ordinary skill in the art

would have been motivated to combine the teaching to introduce a termination site after the sense strand or a unique restriction sequence for cloning purposes.

In addition, it would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to combine the teaching of Fire taken with Ladner, namely to produce an isolated animal cell comprising a construct comprising a structural gene with a stuffer sequence. One of ordinary skill in the art would have been motivated to combine the teaching for studying inhibition in animal cells in vitro using the construct with or without a stuffer sequence.

Therefore the invention as a whole would have been *prima facie* obvious to one ordinary skill in the art at the time the invention was made.

Claims 27, 34, and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fire (US 6,506,559) taken with D'Apice et al. (US 6,849,448). Fire teaches a vector comprising a construct comprising a promoter operably linked to a nucleotide sequence comprising a sense strand and an antisense strand of the target gene (columns 4 and 9). The promoter can be a T7 and T3 promoters (columns 8-9). The nucleotide sequence may be at least 25 or 50 bases (column 8). The vector can be introduced into a cancerous cell, including cancer cells find in humans (column 9-10). A viral vector can be used as the vector (column 9). The cell can comprise a target gene at risk from a pathogen including HIV (columns 4, 8, and 10). The target gene can be an endogenous from in a human cell (columns 4 and 10-11). The structural gene can comprise one or more strands of the nucleotide sequence (column 4). However, Fire does not specifically teach a construct comprising a structural gene comprising a nucleotide sequence

which is substantially identical to the sequence of a target gene, wherein the target gene is alpha 1,3-galactosyltransferase.

However, at the time the invention was made, D'Apice teaches, "human pre-formed xenoantibodies play an important role in the hyperacute rejection response in human xenotransplantation (abstract)." "Such epitopes are formed as the result of activity by the enzyme alpha-1,3 galactosyltransferase (abstract)."

It would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to combine the teaching of Fire taken with D'Apice, namely to produce a construct comprising a structural gene comprising a nucleotide sequence which is substantially identical to the sequence of a target gene, wherein the target gene is alpha 1,3-galactosyltransferase. One of ordinary skill in the art would have been motivated to combine the teaching to study xenoreactivity by inhibition of alpha 1,3-galactosyltransferse in *in vitro* cells.

Therefore the invention as a whole would have been *prima facie* obvious to one ordinary skill in the art at the time the invention was made.

Claims 27 and 34-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fire et al. taken with D'Apice et al as applied to claims 27, 34 and 35 above, and further in view of Draper et al. (US 5496698). However, Fire taken with D'Apice does not specifically a CMV promoter.

However, at the time the invention was made, CMV promoter was well known to one of ordinary skilled in the art as exemplified by Draper (column 8). CMV is a strong constitutive promoter (column 8).

It would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to combine the teaching of Fire and D'Apice in further view of Draper, namely to produce a construct comprising a structural gene comprising a CMV promoter operably linked to a nucleotide sequence which is substantially identical to the sequence of a target gene, wherein the target gene is alpha 1,3-galactosyltransferase. One of ordinary skill in the art would have been motivated to combine the teaching because the CMV promoter is a strong constitutive promoter.

Therefore the invention as a whole would have been *prima facie* obvious to one ordinary skill in the art at the time the invention was made.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 27 and 38 remain and claims 56-61 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-22 of U.S. Patent No. 6,573,099. Although the conflicting claims are not identical, they are not patentably distinct from each other because for reasons set forth in paragraph bridging pages 14-15 of the office action mailed on 3/7/03.

Applicant's arguments filed 12/7/04 have been fully considered but they are not persuasive.

Applicant argues that the instant claims include the limitation "mammalian" while claim 1 and 6 of US Patent 6,573,099 are limited to "animals", which is broader than mammals. Nothing in claims 1 and 6 of '099 would suggest selection of mammals versus any other classes even phyla of animals.

Applicant's argument is not found persuasive because the limitation "mammal" in claim 27 and the limitation "capable of post-transcriptionally delaying, repressing or otherwise reducing expression of a target gene in a mammal cell transfected with the genetic construct by sequence-specific degradation of a RNA transcript of the target gene by an endogenous system of the mammal cell" in instant claims 56-58 and claims dependent therefrom are directed to an intended use. With regard to the specified activity, if a prior art structure is capable of performing the intended use as recited in the claim, then it meets the claim. See, e.g., In re Schreiber, 128 F.3d 1473, 1477, 44 USPQ2d 1429, 1431 (Fed. Cir. 1997).

The term "capable" in the limitation recited in instant claims 27 and 56-58 and claims dependent therefrom does not require that the construct perform the functions recited in the claimed product.

Claims 27, 38, and 56-64 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 34-43, 53-63, and 65 of copending Application No. 10/346,853. Although the conflicting claims are not identical, they are not patentably distinct from each other because both set of claims embrace an isolated genetic construct comprising at least two copies of a structural gene sequence, wherein the structural gene sequence comprise a nucleotide sequence which is identical to at least a region of said target gene, wherein at least two copies of the structural gene sequence are placed under the control of a promoter, wherein one or more copies is placed operably in the sense orientation under the control of at least one promoter.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Furthermore, the following serial numbers of co-pending applications contain claims in which an obviousness-type double patenting rejection would be applied:

10/646,070

11/218,999

11/180,928

10/801,191

10/821,726

It is Applicants' burden to file appropriate terminal disclaimers for all relevant applications listed above. Furthermore, if Applicants are aware of any pending applications or patents, which are not listed above, it is Applicants' duty to disclose these applications or

patents, and to submit an appropriate terminal disclaimer over these applications or patents as pertinent to the instant invention.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

Applicant's arguments, see pages 6-7, filed 12/7/04, with respect to enablement have been fully considered and are persuasive. The rejection of claims 34, 35, 40 and 48 has been withdrawn because of the cancellation of claim and the claimed product can be used for in vitro research purposes.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Whiteman whose telephone number is (571) 272-0764. The examiner can normally be reached on Monday through Friday from 7:00 to 4:00 (Eastern Standard Time), with alternating Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras, SPE – Art Unit 1635, can be reached at (571) 272-4517.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Fax Center number is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Brian Whiteman

BRIAN WHITEMAN
PATENT EXAMINER